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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,055	07/14/2003	Timothy J. Ohara	LSI0054/US/2	7665

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/620,055

Applicant(s)

OHARA ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/13/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed December 04, 2006 have been fully considered but they are not persuasive. As a first matter, while the Examiner acknowledges painstakingly citing numerous passages of both the Jina and Hodges references, he most emphatically did not desperately piece together the rejection.

Applicant refers to column 2, lines 31-41 of Jina apparently as a teaching that the Jina electrode arrangement is constrained to side-by-side electrodes on a non-porous surface. The Examiner respectfully disagrees. The passage in Jina relied by Applicant discloses prior art coagulation sensors that function in a different manner than that of Jina's. In particular, the prior art sensors discussed in column 2, lines 31-41 of Jina measure coagulation from resistance measurements. Jina, in contrast, reacts the blood sample with a reagent and measures current or voltage. Although, conductivity plots are shown in the figures, a fundamental aspect of Jina's use of the sensor involves measuring diffusion characteristics of an electroactive species based on current or voltage measurement. In other words a key aspect of Jina's sensing method is that it relies on electrochemical reactions. See col. 09:16-31; col. 09:51-63; and col. 10:32-40.

Moreover, contrary to Applicant's underlined statement regarding critical emphasis being placed on the geometric orientation of the cell and Applicant's

Art Unit: 1753

statement, "Jina teaches that previous attempts ... has led to the conclusion that geometric orientation of the electrode was critical," Jina states, "The device 10 itself may assume *any* convenient geometric shape as long as the electronics and chemistry described herein are cost effectively contained with acceptable performance. [emphasis added]" See col. 05:25-29. Other than in discussion of the prior art, nowhere does Jina discuss cell geometry (particularly side-by-side electrodes) as being significant for good measurement results.

As for the Hodges reference, the disclosed sensor is not constrained to measuring glucose; this is only an example use. See page 01:03-07. Also, as pointed out in the rejection of claim 21 in the previous Office action both Hodges and Jina make measurements on whole blood sample and both Hodges and Jina disclose the same redox mediator, ferricyanide. Since an important aspect of Jina's method involves measuring diffusion characteristics of a redox species, such as ferricyanide, in whole blood, it is highly relevant that Hodges teaches improving measurements of redox properties by having the working electrode and counter electrode closely spaced together and opposite one another. See page 06:07-15; page 08:12-14; and page 19:20-23.

For the reasons set forth above the rejections of claims 21-30 under 35 U.S.C. 103 are maintained. The rejections of claim 29 and 30 are restated below in light of Applicant's amendment; however, the Examiner's rebuttal above still holds.

Status of the rejections pending since the Office action of August 29, 2006

2. The rejections of claims 21-30 under 35 U.S.C. 103(a) as being obvious over Jina as modified by Hodges are maintained.
3. The rejection of claims 29 and 30 under 35 U.S.C. 112, first paragraph is withdrawn.
4. The rejection of claim 30 under 35 U.S.C. 112, second paragraph is withdrawn.
5. The objection to claims 25 and 27 are withdrawn.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Addressing claim 29, Jina discloses a system for use in determining a change in viscosity of a fluid sample (abstract), comprising

(1) an electrochemical test strip (16) comprising

(a) spaced apart working (64) and reference electrodes (66); and

(b) a reagent mixture comprising:

(i) a redox couple (col. 11:50-54 and col. 4:9-17)

(i) a coagulation agent (col. 11:50-61, col. 9:45-58; col. 10:6-16);

and

(2) a meter (Figure 1).

Jina does not mention (a) having the working and reference electrodes oppositely spaced apart, and (b) having the working and reference electrodes spaced apart from about 50 to 750 μ m.

Hodges discloses an electrochemical cell comprising working and reference electrodes oppositely spaced apart from about 50 to 750 μ m. See Figures 1-4 and the abstract. It would have been obvious to one with ordinary skill in the art at the time of the invention to have the working and reference electrodes oppositely spaced apart from about 50 to 750 μ m as taught by Hodges in the invention of Jina because as taught by Hodges, "This ... allows the diffusion coefficient and concentration of the redox species (mediator) to be measured independently of sample variations and therefore improves accuracy and reliability" (page 6, lines 12-15), Jina discloses using the same redox couple as Hodges (ferricyanide – page 6, lines 7-11 and in Jina col. 11:50-54)

Art Unit: 1753

and measures diffusion properties of the redox couple (col. 9:25-31 and col. 10:36-40), and because the cell of Hodges can be used with blood samples (page 6, lines 16-19).

It should be noted that although the embodiment in Figure 6 of Jina shows separate counter and reference electrodes Hodges states, "For preference the cell comprises a working electrodes and counter/reference electrodes. If a reference electrode separate from a counter electrode is used, then the reference electrode may be in any convenient location in which it is in contact with the sample in the sensor." See page 6, lines 3-6.

Addressing claim 30, Jina discloses a system for use in determining a change in viscosity of a fluid sample (abstract), comprising

(1) an electrochemical test strip (16); and

(2) a meter comprising:

(a) means for applying an electric potential to an electrochemical cell made up of spaced apart working and reference electrodes and comprising a fluid sample (Figures 1, 2, and 6; col. 8:50-58; and col. 7:18-22); and

(b) means for measuring cell current between the spaced working and reference electrodes (vol. 6:54 – col. 7:8).

Jina does not *mention* means for detecting a change in the measured cell current and means for relating the change in measured cell current to a change in viscosity of

Art Unit: 1753

the fluid sample. However, these means are arguably implied or clearly obvious because Jina discloses, "The processor **32** contains a program which includes, but is not limited to, *interpreting* the current off the electrodes, ...[emphasis added]" (col. 7:4-8) and

Until such time when clotting is complete, there may be a slight increase in the current of the clot due to aggregation of the electroactive species in spite of restricted ionic mobility and or diffusion. Such a current time profile is extremely useful in determining the onset of clotting as well as the endpoint of the clotting process and could conceptually provide a very accurate means for determining the onset of clotting as well as the endpoint of the clotting times in PT, APTT and other clotting assays. The sensitivity of these types of current or voltage time measurements is inherent in the direct measurement technique ..." (col. 9:49-61).

In other words, it would have been obvious to one with ordinary skill in the art at the time of the invention to provide in Jina means for detecting a change in the measured cell current and means for relating the change in measured cell current to a change in viscosity of the fluid sample because Jina discloses means for interpreting the measured current and the changes in the current profile reflect different stages of clotting. Thus, clotting can be monitored with such means.

Jina also does not mention having the means for applying an electric potential to an electrochemical cell configured for an electrochemical cell made up of oppositely spaced apart working and reference electrodes. In all of the Jina embodiments the electrodes are on the same plane. See Figures 2-5.

Hodges discloses an electrochemical cell comprising working and reference electrodes oppositely spaced apart from about 50 to 750 μ m. See Figures 1-4 and the abstract. It would have been obvious to one with ordinary skill in the art at the time of

Art Unit: 1753

the invention to have the working and reference electrodes oppositely spaced apart from about 50 to 750 μ m as taught by Hodges in the invention of Jina (and so of course the electrical cell contacts in the meter of Jina oppositely spaced) because as taught by Hodges, "This ... allows the diffusion coefficient and concentration of the redox species (mediator) to be measured independently of sample variations and therefore improves accuracy and reliability" (page 6, lines 12-15), Jina discloses using the same redox couple as Hodges (ferricyanide – page 6, lines 7-11 and in Jina col. 11:50-54) and measures diffusion properties of the redox couple (col. 9:25-31 and col. 10:36-40), and because the cell of Hodges can be used with blood samples (page 6, lines 16-19).

It should be noted that although the embodiment in Figure 6 of Jina shows separate counter and reference electrodes Hodges states, "For preference the cell comprises a working electrodes and counter/reference electrodes. If a reference electrode separate from a counter electrode is used, then the reference electrode may be in any convenient location in which it is in contact with the sample in the sensor." See page 6, lines 3-6.

Final Rejection

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1753

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguera
Primary Examiner
AU 1753
February 8, 2007